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Signed

Dated 7 March 2000

An Executive Agency of the Department of Trade and Industry







## GB9901085.2

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of

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[ADP No. 07627961001]



Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to belp you fill in this form)

THE PATENT OFFICE 20 JAN 1999

The Patent Office

Cardiff Road Newport Gwent NP9 1RH

1. Your reference

HJL/7052

2. Patent application number 9901085.2 (The Patent Office will fill in this part)

20 JAN 1999

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Τινθορρε (Decorative Trims) Ltd Southfield Road, Hinckley, Leicestershire. LE10 1UD.

Dec.
Road, Him

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ACT ACT APPLICATION FILES

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

4. Title of the invention

Bandage

5. Name of your agent (if you bave one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Swindell & Pearson

48 Friar Gate. Derby DE1 1GY

Patents ADP number (if you know it)

00001578001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number (if you know it)

Date of filing (day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing (day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer Yes' if:

a) any applicant named in part 3 is not an inventor, or

b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

See note (d))

YES

Request for preliminary examination and search (Patents Form 9/77)  Request for substantive examination (Patents Form 10/77)  Any other documents (please specify)	I/We request the grant of a patent on the	e basis of this applicati Date 19/1/1999
and search (Patents Form 9/77)  Request for substantive examination (Patents Form 10/77)  Any other documents		
and search (Patents Form 9/77)  Request for substantive examination		
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Statement of inventorship and right to grant of a patent (Patents Form 7/77)		
Translations of priority documents		
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## **Bandage**

This invention relates to bandages. More particularly, but not exclusively, the invention relates to laminated bandages, for example, such bandages for use in the treatment of venous leg ulcers. The invention also relates to bandage systems

The treatment of leg ulcers is traditionally carried out using a four piece bandage system which comprises a first layer of orthopaedic wool, a second layer consisting of a crepe bandage, a third layer consisting of a light pressure bandage, and fourth layer consisting of a cohesive bandage. The application of this system requires complex measurement of arterial pressures and upwards of half an hour to apply it. Moreover, it is difficult to ensure that the pressure applied by the bandage at various regions is correct.

According to one aspect of this invention there is provided a bandage comprising a first absorbent layer for arrangement adjacent the skin of a patient, and a second absorbent layer on the first absorbent layer, the second absorbent layer having a greater propensity for absorption of fluids than the first absorbent layer, whereby when the bandage is arranged over a wound of a patient, the first absorbent layer can absorb fluid from the wound and the second absorbent layer can absorb said fluid from the first absorbent layer.

The bandage advantageously further includes a third layer on the second absorbent layer on the opposite side thereof to the first absorbent layer, the third layer may be an absorbent layer and preferably has a lower propensity for absorption than the second layer.

In one embodiment, the third layer is permeable to vapour, thereby allowing the skin to breathe, and may have substantially the same absorbency as, or less absorbency than, the first absorbent layer. The third layer may be formed of the same material as the first absorbent layer. Alternatively, the third layer may be substantially impermeable to liquid but permeable to vapour.

The bandage may be shaped to conform substantially to a limb of the patient. In the preferred embodiment, the bandage is shaped to conform to the lower leg of the patient. The bandage may be shaped to conform to the foot of a patient or to the lower leg and foot of a patient. The bandage may have a first part shaped to conform to the lower leg of a patient and a second part shaped to conform to the foot of a patient.

The bandage may have stitching along the region thereof conforming to the calf region of the leg, and may have stitching along the region conforming to the heel region of the foot. Stitching may also be provided to conform to the two region of the foot.

The bandage may have opposite side edges wherein the side edges can be overlapped to a desired degree to fit the bandage to the patients' limb. Securing means may be provided to secure the edge regions together. The securing means is preferably in the form of an adhesive tape. Suitable tabs and/or flaps may also be provided to ensure appropriate overlap.

The first absorbent layer-may comprise a polyester viscose material. The second absorbent layer may comprise a polyester felt, suitably an hydrophilic polyester felt. Alternatively, the second absorbent layer may comprise cotton wool. The third layer may be a polyester viscose material.

The preferred embodiment of the invention has the advantage that it can be used to replace the first two layers of the system described in the introduction.

According to another aspect of this invention there is provided a bandage system comprising a first bandage as described above and a second bandage being a compression bandage, the second bandage comprising a sheet of elastic material and means for releasably maintaining the sheet of elastic material in a stretched condition around a patient's limb. Thus, the first bandage is intended to be applied over the skin of the patient's limb, and the second bandage is intended to be applied over the first bandage.

Preferably, the second bandage is formed from a rubber or rubber-like material, and may be formed a synthetic rubber, for example neoprene.

The means for maintaining the material around the patient's limb may include an outer attachment associated with a side edge region of the sheet. Preferably, the outer attachment comprises a plurality of tabs provided along substantially the length of said side edge. The tabs are preferably so provided along the length of said side edge that there are substantially no gaps between adjacent tabs when the bandage is correctly applied to a patient's limb. One part of a hook and fleece fastening means may be provided on an inner face of each tab. The other of said hook and fleece fastenings may be provided on the sheet.

Preferably, the hook fastening is provided on each tab and the fleece fastening is provided on the sheet. In the preferred embodiment, the sheet comprises an outer layer formed of a plush material, said plush material constituting the fleece fastening. It will be appreciated that any other suitable fastening means may be provided on the tabs, for example a buckle or other suitable quick release device.

Each tab is preferably stretchable, whereby when the second bandage is applied to the limb of a patient, the degree of stretch of the sheet material and of the tabs determines the pressure applied to the limb at the respective tab.

Preferably, the second bandage includes visual indication means to indicate whether the correct pressure is applied to the limb by the bandage. The visual indication means is preferably adapted to indicate the extent to which the respective tab is stretched. Preferably, the visual indication means comprises a shape applied to at least some, and preferably each, of the tabs to indicate that the correct pressure is applied when the shape alters in a recognisable way. For example, the shapes may be in the form of an oblong, which alter to a square when the correct pressure is achieved.

The visual indication means may be so provided such that each indicates the same extent of stretch and correspondingly, the same pressure, or they may indicate different extents of stretch. For example, the visual indication means may

be so arranged to indicate a gradation of pressure from one end of the bandage to the other.

The preferred embodiment of the bandage system has the advantage that it can replace all four layers of the system described in the introduction and is much simpler and faster to apply. Moreover, it is possible using the preferred embodiment to achieve the desired pressures simply and with accuracy.

At least one embodiment of the invention will now be described by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a plan view of a bandage;

Fig. 2 is a diagrammatic sectional view of a part of the bandage shown in Fig. 1, showing the laminations

Fig. 3 is a diagrammatic side view of a bandage according to a second embodiment of the invention, fitted onto a patient's leg;

Fig. 4 is a diagrammatic side view of the bandage of Fig. 3, not fitted onto a patient's leg;

Fig. 5 is a diagrammatic perspective view of the bandage of Fig. 3, wrapped around as if to be fitted onto a patient's leg;

Fig. 6 is a partial diagrammatic plan view, showing an upper part of the bandage of Fig. 3, laid out flat in its unstretched state; and

Fig. 7 is a plan view of a flat piece of neoprene cut into a shape suitable for stitching up into a bandage according to the second embodiment of the invention.

Referring to Figs. 1 and 2, an absorbent bandage 10 is shown which is particularly suitable for venous leg ulcers, and which comprises a first or inner

layer 12, a second or middle layer 14, and a third or outer layer 16 (see particularly Fig. 2). The inner layer 12 is formed of an absorbent material, for example a polyester viscose material. The outer layer 16 is also formed of an absorbent material, which may also be a polyester viscose material. The middle layer 14 is also formed of an absorbent material which has a greater propensity for absorption than the material from which the inner layer 12 is formed. In the embodiment shown, the material from which the middle layer 14 is formed is an hydrophilic polyester felt. Alternatively, the middle layer 14 may be formed from another absorbent material, for example, cotton wool.

Referring specifically to Fig. 1, the absorbent bandage 10 is formed of a shaped sheet of a particular configuration that is intended to conform to the lower leg and foot of a patient. In Fig. 1, the bandage is shown in a flat condition suitable for stitching into a bandage conforming as aforesaid to the shape of the lower leg and foot of a patient. The absorbent bandage 10 comprises a leg portion 18 which is adapted to fit around the lower leg of a patient, and a foot portion 20 which is adapted to fit around the foot of a patient. A heel portion 21 connects the leg portion 18 to the foot portion 20.

The leg portion 18 is formed of first and second sections 18A, 18B, which are each defined along one side by respective edges 19 intended to be stitched together along their length. The particular profiles of the edges 19 are selected to ensure that the first part 18 conforms closely to the shape of the lower leg of a patient.

For the sake of clarity, the use of dashed lines in the drawings adjacent an edge is intended to represent that the edge should be stitched to an adjacent corresponding edge.

A heel portion 21 is provided between the leg and foot portions 18, 20 and has edges 21A, 21B. It is intended that the edges 21A are stitched together, and the edges 21B are also stitched together. In this way, in the resulting bandage 10, the heel portion 21 conforms to the heel of the patient. Further edges to be

stitched are represented at 22A and 22B in the foot portion 20. These enable the foot portion 20 to conform to the shape of the patient's foot.

It will be seen that the first section 18A of the leg portion 18 is somewhat larger than the section 18B. This ensures that there is sufficient material for overlap so that the bandage 10 can fit any size of leg. When the bandage 10 is applied to the patient's lower leg, the second section 18B is first wrapped around the patient's leg and the first section 18A is then wrapped over the second section 18B. If necessary, the first section 18A can be trimmed to the appropriate size. In this way, the leg portion 18 can be adjusted to fit around the patient's leg comfortably. Appropriate adhesive tape (not shown) can be used to attach the section 18A to the section 18B.

The foot portion 20 comprises first and second sections 20A, 20B. The first section 20A comprises a tab 26, and the second section 20B comprises an outwardly extending portion 28. It is intended that the second section 20B is first wrapped over the top of the patient's foot, and the first section 20A wrapped over the second section 20B. The portion 28 is provided to ensure that the bandage 10 fully covers the top of the foot. Appropriate adhesive tape (not shown) can then attach the first section 20A to the second section 20B.

The first section 18A also comprises a lower portion 25. When the bandage is fitted to a patient's foot, lower portion 25 overlies the foot and the tab 26 overlaps the lower portion 25. The tab 26 is attached thereto by appropriate adhesive tape (not shown).

When the bandage has been fitted to the patient, it fits snugly around the patient's lower limb and foot, covering the venous ulcer to absorb any liquid secreted from the wound. No pressure is applied to the leg by the bandage 10.

Figs. 3 to 7 illustrate a compression bandage 110 for use with the laminated bandage 10 to form a bandage system.

The compression bandage 110 includes an upper part having a body 112 including a sheet of perforated neoprene. The perforations are not illustrated in the drawings, but are approximately 2mm in diameter, and 10mm apart. The perforations allow the leg to breathe, i.e. they allow moisture to leave a patient's leg through the bandage 110. An inner side (in use) of the neoprene is covered with a soft nylon lining, which is comfortable against a patient's leg. The nylon is bonded to the neoprene layer. An outer side (in use) of the neoprene is covered with a layer of cotton plush material, also bonded to the neoprene layer, the function of which is described in more detail hereinafter.

The body 112 is bounded by an upper edge 114. A lower edge 115 of the body is stitched to a foot portion 117, which is also made from perforated neoprene enclosed within inner and outer layers of nylon and plush cotton respectively.

The body 112 is made up of two shaped sheets of neoprene 150 and 152 (see Figs. 4 and 6). The sheets 150 and 152 are cut with curved edges 154 which are stitched together to form the body 112. This results in a body shape which fits snugly around a patient's leg, taking account of variations in leg diameter between the ankle and calf.

The foot portion 117 is made from a simple sheet of neoprene but small slits are cut from the neoprene and the resulting exposed edges 155 joined with stitching 156 to form an appropriately shaped foot portion.

Fig. 6 illustrates a flat piece of neoprene cut into a shape suitable for stitching into the bandage 110, showing the places where stitching occurs to form the shaped bandage. Fig. 9 shows the body 112 and foot portions 117 joined but they may be formed from separate sheets of material.

The stitching on both the body 112 and foot portion 117 is omitted from Fig. 8, for the sake of clarity.

Extending between the upper and lower edges 114 and 115 of the body 112 are side edges 116A and 116B. The side edge 116A is substantially straight and the side edge 116B slightly scalloped. The foot portion 117B includes corresponding straight and scalloped side edges 119A and 119B respectively. Affixed to the side edges 116A are a plurality of attachments 122 consisting of rectangular tabs of material provided with VELCRO (trade mark) hooks on their inner-sides. The attachment 122 are each approximately 50mm in width (along the length of the patient's leg in use) and 120mm in length (around the patient's leg in use) in their unstretched states. The attachments 122 are affixed to the body 112 by two rows of stitching 132, shown in Fig. 7 and on the uppermost attachment only in Fig. 6. The attachments 122 are made of stretchy nylon material.

The foot portion 117 is also provided with similar attachments 122 affixed to the side edge 199A and a narrower end attachment 123.

Fig. 6 shows the bandage system in place on a patient's leg and Fig. 8 illustrates diagrammatically the shape of the bandage 110 during application to the leg. To apply the bandage system, the laminated bandage 10 is first applied to the leg as described above. The compression bandage 110 is then applied over the bandage 10, as follows. The compression bandage 110 is wrapped around the leg and the edge 116A is pulled over the edge 116B such that the two overlap as illustrated by the arrows in Fig. 8. The bandage is stretched around the leg, and the attachments 122 are laid onto the cotton plush material such that their hooks engage the material. In the stretched condition, the hooks open up slightly and engage the cotton plush material very firmly.

It is most important that the compression bandage 110 applies the correct pressure all along the leg from the top of the calf to the foot. The preferred pressure decreases gradually from about 35 to 40mmHg at the ankle to about 17 mmHg at the top of the calf. Rectangles 136 provided on the attachments 122 become square when the correct pressure is achieved. Such rectangles may be provided on all the attachments to ensure that the correct pressure is applied along the entire leg. It may be seen that the rectangles 136 of Fig. 8 become square in

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Fig. 6, when the correct pressure is applied by the bandage to the leg.

Because the attachments 122 are provided essentially along the whole length of the compression bandage 110, gradually varying pressure is exerted along the patient's leg. No lines of high or low pressure are established if the bandage is used correctly.

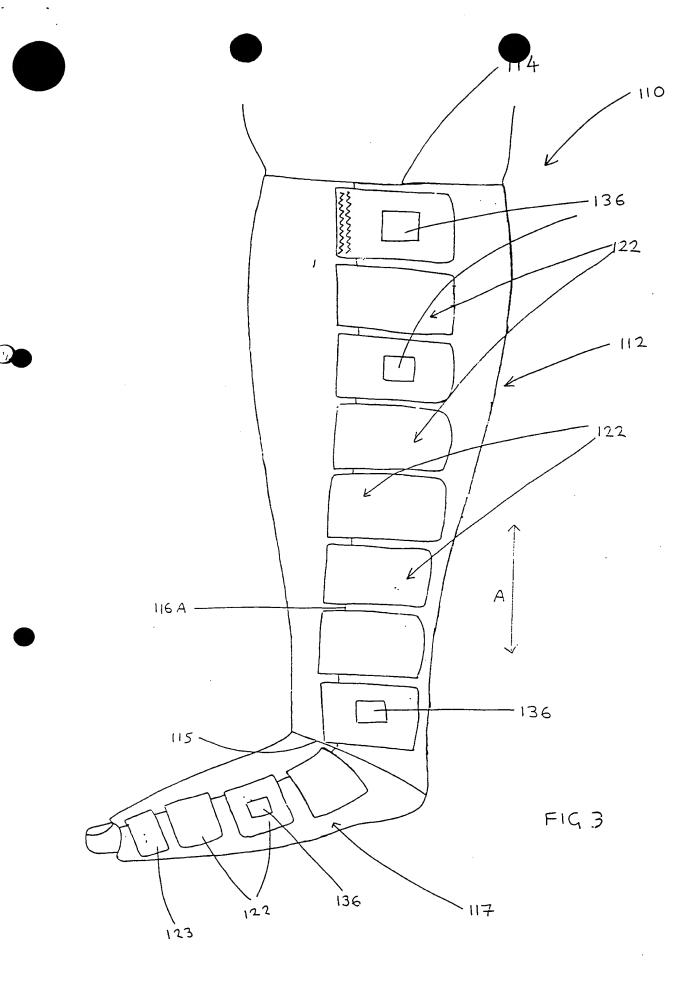
It will be appreciated that in certain circumstances the absorbent bandage could be used in situations other than for the treatment of venous leg ulcers. In such cases, the use of the compression bandage would not be required. Further if the absorbent bandage is used to treat wounds other than on the leg, its configuration would be different.

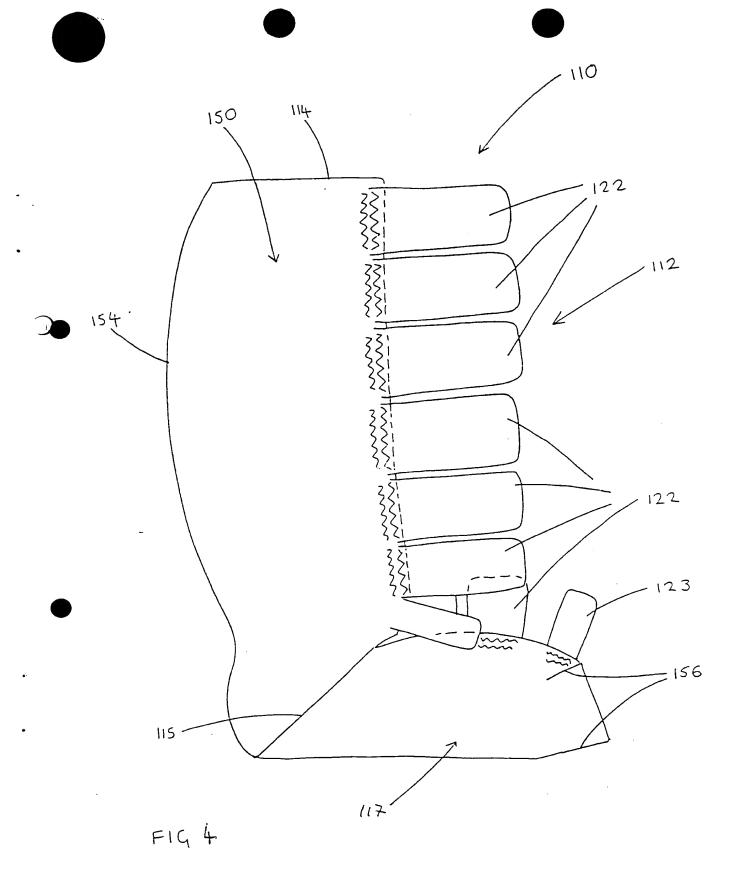
Various modifications may be made to the above invention while still falling within its scope. The body of the compression bandage 12 need not be manufactured from neoprene but may be made from any suitable stretchy material, for example material incorporating rubber or elastane. The attachments need not incorporate hook or hook and fleece fastenings but may include tapes, cords or other similar materials attached together by hooks, loops, buckles or similar devices. The rectangle 136 may be replaced with any means for indicating the extent to which the body has stretched. For example, any shape may be printed onto the body. A plurality of such shapes may be used, for example, one adjacent to each projection to ensure an even pressure is exerted throughout the entire bandage. The bandage may be designed to be used at a single optimum pressure or it may be provided with different indications to provide different pressures depending on the circumstances. For example three adjacent rectangles could become square at respectively different pressures.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

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Fig 2





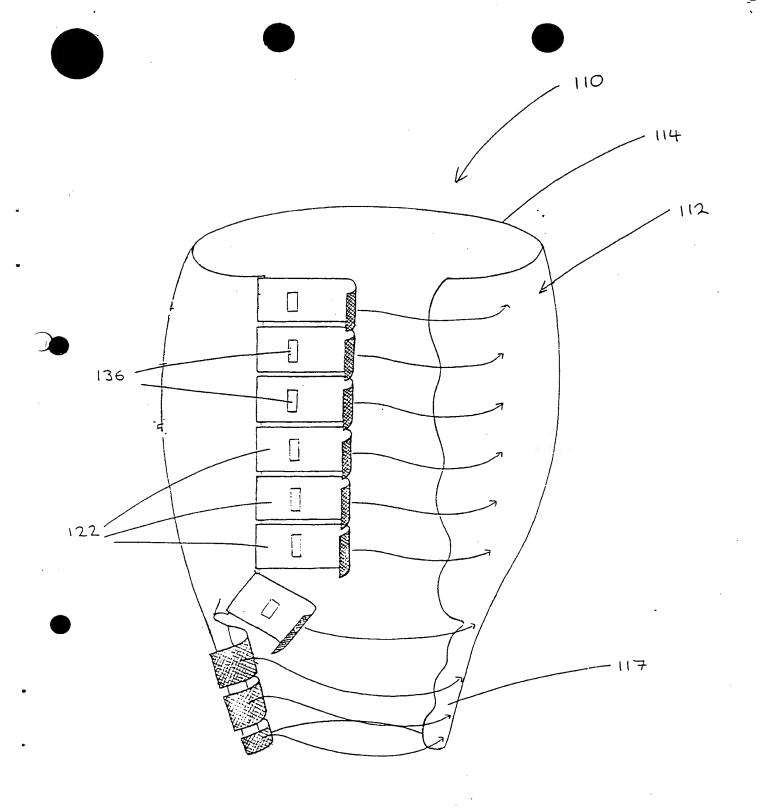


FIG 5

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